U.S. FOOD & DRUG ADMINISTRATION

September 15, 2021

Kerberos Proximal Solutions, Inc.
Tom Mason
Vice President
10600 North Tantau Ave.
Cupertino, California 95014

Re: K062275
Trade/Device Name: Rinspiration System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA

Dear Tom Mason:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 20, 2006. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2021.09.15 09:21:58 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2006

Kerberos Proximal Solutions
C/O Mr. Tom Mason
Vice President, Regulatory Affairs and Quality Assurance
10600 N. Tantau Avenue
Cupertino, CA 95014

Re: K062275
Trade/Device Name: Kerberos Proximal Solutions Rinspiration System
Regulation Number: 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: II
Product Code: DXE
Dated: September 1, 2006
Received: September 5, 2006

Dear Mr. Mason:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The Kerberos Proximal Solutions Rinspiration System may result in secondary removal of thrombus while using the Rinspiration System in a manner consistent with the indications and instructions for use presented in the product labeling; however, please note the following: The safety and effectiveness of the Kerberos Proximal Solutions Rinspiration System has NOT been established for the exclusive or sole use of thrombectomy or embolic protection. Complications

from the use of this device in this manner could lead to death, permanent impairment, and/or the need for emergency medical intervention.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 062275

Device Name: Kerberos Proximal Solutions Rinspiration Catheter System

Indications for Use:

The Kerberos Proximal Solutions Rinspiration Catheter System is intended to infuse physician specified fluid and remove/aspirate fresh, soft emboli and thrombi from the coronary and peripheral vasculature.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachner

(Division Sign-Off)
Division of Cardiovascular Devices

510(K) Number K062275

SECTION 4
510(k) Summary

This 510(k) summary for the KPS Rinspiration Catheter System is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant Information

Kerberos Proximal Solutions, Inc.
10600 North Tantau Avenue
Cupertino, CA 95014
Contact Person: Tom Mason
Phone Number: (408) 253-3319
FAX Number: (408) 253-6118

Trade Proprietary Name

Rinspiration Catheter System

Device Classification

The FDA Cardiovascular Devices Panel has classified devices for the KPS Rinspiration System as follows:

Classification Name	Class	21 CFR	Product Code
Embolectomy Catheter	II	870.5150	DXE

Predicate Device

Name: Rinspiration System
Manufacturer: Kerberos Proximal Solutions, Inc.
Status: Post-enactment
510(k) # K050130

Indications for Use

The Indications for Use for the Rinspiration Catheter System remains identical to the cleared device indication.

Product	Indication for Use
Kerberos Proximal Solutions Rinspiration Catheter System Applied for in this premarket notification	PROPOSED: The Kerberos Proximal Solutions Rinspiration Catheter System is intended to infuse physician specified fluid and remove/aspirate fluid, fresh, soft emboli and thrombi from the coronary and peripheral vasculature.
Kerberos Proximal Solutions Rinspiration System K050130	The Kerberos Proximal Solutions Rinspiration System is intended to infuse physician specified fluid and remove/aspirate fluid, fresh, soft emboli and thrombi from the coronary and peripheral vasculature.

Device Description
The system consists of a Rinspiration® Catheter, and a Rinspirator® with accessories. The Rinspiration Catheter is a multi-lumen, rail configuration catheter that has perforations located near the distal end of the catheter to dispense an infusible fluid. The Rinspiration Catheter will be placed in the vasculature of a patient over a guide wire. The catheter includes a radiopaque marker band at the distal tip and two radiopaque marker bands designating the infusion portion of the catheter. The catheter has a hub on the proximal end that allows access to the infusion and aspiration lumens. The Rinspirator and accessories is a sterile, single-use mechanical device. This hand activated device allows for simultaneous infusion and aspiration of fluids at the treatment site. The device activates two syringes, one for infusion and one for aspiration. This simultaneous infusion and aspiration action is known as "Rinspiration®."

The only difference between the cleared Rinspiration System and the Rinspiration Catheter System with Fluid Infusion Stopcock Port is the addition of a 4-way stopcock and a co-extruded paratube that replaces the infusion and aspiration lines.

The fluid infusion stopcock port consists of a 4-way stopcock which attaches directly to the infusion check valve. This addition provides the user another means to infuse physician specified fluids.

In order to streamline the appearance of the Rinspiration Catheter System, a co-extruded paratube replaces the infusion and aspiration lines.

Substantial Equivalence
The KPS Rinspiration Catheter System is substantially equivalent to the predicate device with regard to intended use, function, materials, and sterilization method.

All necessary testing was performed on the Kerberos Proximal Solutions Rinspiration Catheter System to ensure the product is substantially equivalent to the predicate device and to ensure that the Rinspiration Catheter System does not have any differences that have a significant effect on safety or effectiveness.

Summary
Based on the intended use and product performance information provided in this notification, the subject device is safe and effective when used in accordance with its Instructions for Use and has been shown to be substantially equivalent to the currently marketed predicate device.